510(k) Summary
Spinal Elements Posterior Cervical / Thoracic Spinal System

JUL 30 2012

510(k) Number: K120467

Manufacturer Identification

Submitted by:

Spinal Elements, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-0121
761-607-0125 (fax)

Contact Information:

Benjamin A. Kimball
Regulatory Affairs Manager
Spinal Elements, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-1816
Bkimball@spinalelements.com

Date Prepared: July 26, 2012

Device Indentification

Proprietary Name	Spinal Elements Posterior Cervical / Thoracic Spinal System
Common Name	Spinal Interlaminal Fixation and Spinal Intervetebral Fixation Orthosis and/or Pedicle Screw System
Device Classification	21 CFR 888.3050 and / or 21 CFR 888.3070
Classification Name	Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Proposed Regulatory Class	Class III
Device Product Code:	MNI, KWP, NKB

Purpose of this 510(k)

This 510(k) seeks clearance for a new system.

Device Description

The Spinal Elements Posterior Cervical/Thoracic System consists of a variety of fixation devices that are attached to the spine by means of screws and hooks placed in/or on the pedicles or posterior elements of the various vertebrae, rods that span the distance between the screws/hooks, and transverse connectors. Screws are intended for attachment to the thoracic (T1-T3) spine only. All components of the system are manufactured from titanium alloy (Ti-6Al-4V conforming to ASTM F 136 or ISO 5832-3). The system achieves fixation by the mechanical joining of the rods, screws, hooks, and connectors. A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient.

Intended Use of the Device

The Spinal Elements Posterior Cervical/Thoracic Spinal System is intended for posterior fixation of the cervical and thoracic spine (C1-T3) for the following conditions: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies); spondylolisthesis; spinal stenosis; trauma (fracture/dislocation); failed previous fusion; tumors.

The use of polyaxial pedicle screws is limited to placement in T1-T3 for treating thoracic conditions only. The screws are not intended to be placed in the cervical spine.

Performance Data

Non-clinical, mechanical testing was performed in accordance with ASTM F1717 to determine the performance profile of the device. Testing included:

- Static compression testing
- Dynamic compression testing
- Torsion testing

All test results indicate the system will perform as intended.

Substantial Equivalence

Spinal Elements Posterior Cervical/Thoracic Spinal System is substantially equivalent to Alphatec's Solanas® Posterior Stabilization System (K052201 and K071380), Depuy Spine's Summit® Ocipito-Cervico-Thoracic (OCT) Spinal System (K002733 and K010681), and SeaSpine's Sierra System (K062934) in indications, general design features, performance, function, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Spinal Elements, Incorporated
% Mr. Benjamin A. Kimball
Regulatory Affairs Manager
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

Re: K120467
Trade/Device Name: Spinal Elements Posterior Cervical/Thoracic Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, KWP
Dated: July 18, 2012
Received: July 19, 2012

Dear Mr. Kimball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) K:120467

Device Name: Spinal Elements Posterior Cervical / Thoracic Spinal System

Indications for Use:
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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120467